



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

10002/0100

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APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/356,675	07/19/99	005	WILSON, M	12/11/00
First Named Applicant FALLAUX, 35 USC 154(b) term ext. 0 Days.				

TITLE OF INVENTION: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT ADENOVIRUS TO BE USED IN GENE THERAPY

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
392508	435-455.000	017	UTILITY	YES	9620.00	03/12/01

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

- I. Review the SMALL ENTITY status shown above.  
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
  - A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
  - B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

- II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.
- III. All communications regarding this application must give application number and batch number.  
Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

**PATENT AND TRADEMARK OFFICE COPY**

# Notice of Allowability

Application No.  
09/356,575

Applicant(s)  
Fallaux et al.

Examiner  
Wilson, Michael C.

Group Art Unit  
1633



All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☐ This communication is responsive to \_\_\_\_\_.

☒ The allowed claim(s) is/are 18-22 renumbered 1-5.

☐ The drawings filed on \_\_\_\_\_ are acceptable.

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☒ received in Application No. (Series Code/Serial Number) 08/793,170.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☒ Applicant MUST submit NEW FORMAL DRAWINGS

☒ because the originally filed drawings were declared by applicant to be informal.

☐ including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. \_\_\_\_\_.

☒ including changes required by the proposed drawing correction filed on Nov 29, 2000, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 and 6

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☐ Interview Summary, PTO-413

☒ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☒ Examiner's Statement of Reasons for Allowance

# 15/B  
10/8/00

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### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Allen Turner on 8-29-00.

The application has been amended as follows:

✓  
Please cancel claims 1-17.

Please add the following claims.

B' 18. A method of making replication-defective adenovirus lacking functional adenoviral E1A and E1B proteins comprising a) providing a primary cell comprising a first nucleic acid sequence encoding functional E1A protein and E1B protein but not pIX protein; b) transfecting said cell with a second nucleic acid sequence comprising at least one functional adenoviral encapsidating signal and at least one functional adenoviral inverted terminal repeat, wherein said second nucleic acid sequence does not encode functional adenoviral E1A or E1B; and further wherein said first and second nucleic acids sequences lack overlapping sequences, the overlapping sequences otherwise enabling homologous recombination leading to replication competent adenovirus in said

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cell; c) culturing the transfected cell; and d) harvesting replication-defective adenovirus lacking functional adenoviral E1A and E1B from the cultured cell.

B' CONT. 2. The method according to claim 18, wherein said second nucleic acid sequence is in linear form and comprises functional Inverted Terminal Repeats at or near both termini.

3. The method according to claim 18, wherein said second nucleic acid sequence is DNA.

4. The method according to claim 18, wherein the first or second nucleic acid sequence comprises a mutation in the E2A adenoviral gene that encodes a temperature sensitive gene product.

5. The method of claim 18, wherein the primary cell is of human origin.

### *Reasons for Allowance*

The following is an examiner's statement of reasons for allowance: the claims are free of the prior art of record because the prior art of record does not teach or suggest a method of making replication-defective adenovirus lacking functional adenoviral E1A and E1B proteins comprising a) providing a primary cell comprising a first nucleic acid sequence encoding functional E1A protein and E1B protein but not pIX protein; b) transfecting said cell with a second nucleic acid sequence comprising at least one functional adenoviral encapsidating signal and at least one functional adenoviral inverted terminal repeat, wherein said second nucleic acid sequence does not encode functional adenoviral E1A or E1B; and further wherein said first and second nucleic acids sequences lack overlapping sequences, the overlapping sequences otherwise

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enabling homologous recombination leading to replication competent adenovirus in said cell; c) culturing the transfected cell; and d) harvesting replication-defective adenovirus lacking functional adenoviral E1A and E1B from the cultured cell as claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### ***Terminal Disclaimer***

The terminal disclaimer filed on 9-8-00, paper number 9, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 5,994,128, application 08/793,170, filed 2-18-97, has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### ***Information Disclosure Statements***

The Information Disclosure Statements filed 7-19-99, and 4-4-00, papers number 4 and 6 respectively, have been considered and made of record. The Information Disclosure Statement filed 7-19-99, paper number 5, has been entered but does not include a PTO-1449; however, the pending patents listed in paper 5 have been noted.

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*Drawings*

The corrected drawing of Fig. 15 was received on 11-29-00. This drawing is acceptable and should be submitted formally.

*Sequence Listing*

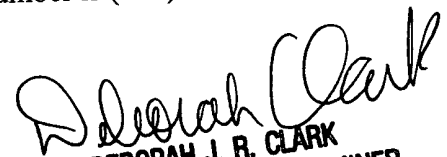
The sequence listing filed 11-29-00, paper number 13, has been entered. The CRF contained errors that were corrected by STIC. "Hard returns" were inserted where needed throughout the sequence listing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is (703) 305-0120. The examiner can normally be reached on Monday through Friday from 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 305-0196.

Michael C. Wilson

  
DEBORAH J. R. CLARK  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

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